CDRH Executive Briefing
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Postmarket Outreach
and a note on Harmonization

Larry Kessler, Sc.D.,Director
Office of Surveillance and Biometrics
Lireka P. Joseph, Dr.P.H., Director
Office of Health and Industry Programs

Adopting Recommendations from the Global Harmonization Task Force SG2: Final Documents

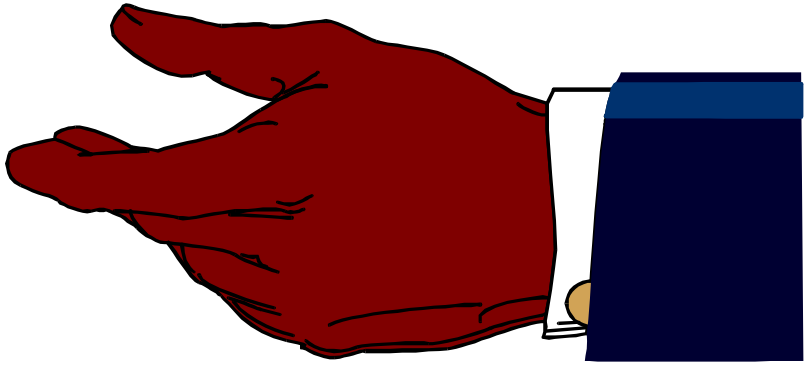
- ***N21: Adverse event reporting rules - Designed for manufacturers to make one decision about whether an event is reportable worldwide.***

Key Changes to Medical Device Reporting Rules

- **Documented service life of the device**
- **No injury but:**
  - **Out of box failure**
  - **Single fault protection operates correctly**
  - **Remote likelihood**
- **Expected and foreseeable side effects**

Postmarket Outreach

- **New initiatives driven by postmarket concerns**
  - **Examples of outreach**
  - **New program at FDA**
- **Although all of CDRH involved, OHIP and OSB tend to lead**



Outreach Examples

- Latex Teleconference - June 1998
  - Substantial evidence of latex allergy problems
  - Largest ever outreach using satellite broadcast
- Hospital Bed Rails & the Vulnerable Patient
  - Multi-agency and organization meeting April 1999
  - Motivated by concerns over hospital bed entrapment
- PROUD 2000
  - CDRH seeking input on user issues from clinical community

STAMP

- Systematic Technology Assessment of Medical Products (STAMP)
- Began at CDRH 1998
- Purpose -- to provide clinicians, consumers, and industry with product information
- We hope this will lead to optimal use of medical devices and improved or safer patient outcomes

STAMP Criteria

- Products generally marketed for some time
- CDRH aware of concerns related to use (but not needing current regulatory action)
- CDRH generally has information that should be shared with users and consumers
- Focus on the dissemination of information to appropriate audiences using any vehicle

STAMP Examples

- Lyme disease test kits
- Cerebrospinal Shunt Technology: Challenges and Emerging Directions
- Whole blood coagulation standardization workshop
- New effort:
  - Liposuction

Postmarket Outreach: The future

- Postmarket efforts contribute to assurance of safety and effectiveness of marketed devices
- As one of FDA's risk management strategies postmarket outreach efforts are part of pre & postmarket evaluation throughout the device life cycle